

MAY - 1 2001

510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Welcon, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Welcon chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name: Welcon Sterile Water for Device Irrigation
Welcon Sterile 0.9% Normal Saline for Device Irrigation

Owner/Operator: Welcon, Inc.
99 Hartford Avenue
Providence, RI 02909

Distributed by: Welcon, Inc.
4909 Airport Freeway, Suite 100
Fort Worth, TX 76117

Manufacturing Site: Welcon, Inc.
99 Hartford Avenue
Providence, RI 02909

Device Generic Name: Sterile water/sterile saline for device irrigation

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (80JOL).

Predicate Devices: Sterile Water for Irrigation
0.9 % Sterile Saline for Irrigation
Welcon, Inc.
Providence, RI 02909
K973734

Sterile Water for Irrigation
0.9 % Sterile Saline for Irrigation
Orion, Inc.
Palm Harbor, FL 34682
K943828, K943832, K943833, K943834

Product Description:

The Welcon Sterile Water and Sterile 0.9% Normal Saline for Device Irrigation are individual, single-use 100 ml. bottles of fluid intended to be used for irrigation. The individual container consists of a plastic bottle with a heat-sealed, adhesive-backed foil lid and a screw cap.

Indications for Use:

The sterile water and sterile saline are indicated for device irrigation only.

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Safety and Performance:

Substantial equivalence for these devices was based solely on design characteristics; no performance or safety data was included in this premarket notification. The materials, performance specifications and essential design characteristics of the Welcon devices are identical to those of the Intermed predicate devices. USP bacterial endotoxin testing was performed to verify that the sterile water and saline solutions conform with USP requirements.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Welcon Sterile Water and Sterile 0.9% Normal Saline for Device Irrigation have been shown to be safe and effective for its intended use.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Welcon, Incorporated
C/O Ms. Pamela Papineau
Consultant
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K003402
Trade/Device Name: Welcon Sterile Water for Device
Irrigation; Sterile Saline for Device Irrigation
Regulation Number: 880.6740
Regulatory Class: II
Product Code: JOL
Dated: February 2, 2001
Received: February 5, 2001

Dear Ms. Papineau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

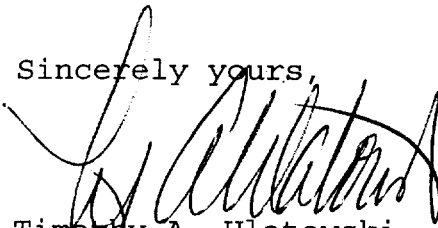
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003402Device Name: Sterile Water for Irrigation/Sterile 0.9% Normal Saline for Device Irrigation

Indications for Use:

The Welcon Sterile Water for Irrigation and Sterile 0.9% Normal Saline for irrigation are indicated for use in device irrigation procedures. The sterile water and saline are not indicated for injection.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the -Counter Use ☐

Patricia Cucenta

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital DevicesDevice Number K003402

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